

26. A method of treating one or more disease states selected from: Alcoholism, Anxiety, Depression, Obsessive Compulsive Disorder, Panic Disorder, Chronic Pain, Obesity, Senile Dementia, Migraine, Bulimia, Anorexia, Social Phobia, Pre-Menstrual Syndrome (PMS), Adolescent Depression, Trichotillomania, Dysthymia and Substance Abuse, which comprises administering an effective amount of a controlled and delayed release formulation of claim 25 to a sufferer in need thereof.

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REMARKS

Claims 9 to 24 are pending in the application. Claims 14 to 19 and 22 to 24 are allowed. Claims 9 to 13, 20 and 21 are rejected under 35 U.S.C. § 102(b). Claims 9 to 13, 20 and 21 are rejected under 35 U.S.C. § 103(a). Applicants request reconsideration and withdrawal of the rejections in view of the above amendments and the reasons set forth herein.

I. The Rejection of Claims 9 to 13, 20 and 21 Under 35 U.S.C. §102(b)

Claims 9 to 13, 20 and 21 are rejected under 35 U.S.C. § 102(b) as being anticipated by Johnson. Johnson is indicated as teaching formulations of paroxetine, including slow release methods or enteric coated tablets, in the treatment of bulimia and anorexia.

Applicants contend that the broad general descriptions of formulations in Johnson fails to anticipate the specific formulations of the instant invention. Notwithstanding, applicants claims, as amended, are directed to formulations that are both delayed and controlled. As indicated on page 1 of the specification (lines 22 to 30), controlled release means a formulation in which the active is released at a slower rate than from a conventional immediate release product and delayed release means the active is released at a later time than from a conventional immediate release product. As indicated on page 2 of the specification (lines 8 to 10), a delayed release formulation can release the active in a different location in the digestive tract. For example, in the small intestine and not in the stomach.

Applicants claims, as amended, are directed to formulations that are both delayed and controlled. Nothing in Johnson teaches or suggests combining delayed release and controlled release technologies in a single formulation containing paroxetine. As such, nothing in Johnson anticipates or renders obvious the currently pending claims.

Applicants contend that nothing in Johnson anticipates their invention as currently claimed. Applicants respectfully request that the rejection here be withdrawn.

II. The Rejection of Claims 9 to 13, 20 and 21 Under 35 U.S.C. §103(a)

Claims 9 to 13, 20 and 21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Johnson. Johnson is indicated as teaching formulations of paroxetine, including slow release methods or enteric coated tablets, in the treatment of bulimia and anorexia. Applicant's disclosed advantage of a reduction in the incidence of nausea and vomiting is considered obvious in view of Johnson's treatment of bulimia and anorexia.

Applicants contend that the broad general descriptions of formulations in Johnson fails to render obvious the specific formulations of the instant invention.

Notwithstanding, applicants claims, as amended, are directed to formulations that are both delayed and controlled. As indicated on page 1 of the specification (lines 22 to 30), controlled release means a formulation in which the active is released at a slower rate than from a conventional immediate release product and delayed release means the active is released at a later time than from a conventional immediate release product. As indicated on page 2 of the specification (lines 8 to 10), a delayed release formulation can release the active in a different location in the digestive tract. For example, in the small intestine and not in the stomach.

Applicants claims, as amended, are directed to formulations that are both delayed and controlled. Nothing in Johnson teaches or suggests combining delayed release and controlled release technologies in a single formulation containing paroxetine. As such, nothing in Johnson renders obvious the currently pending claims.

Moreover, applicants contend that the Examiner is misconstruing the teaching in Johnson regarding the treatment of anorexia and bulimia as reading on their disclosed

advantage. Johnson does not teach or disclose the nausea and vomiting associated with paroxetine administration. Johnson discloses that paroxetine may be used to treat bulimia and anorexia. Bulimia and anorexia are not associated with nausea. To the extent that bulimia and anorexia are associated with vomiting, this vomiting is self induced in order to negate excessive calorific intake caused by binge eating (bulimia) or to achieve weight loss (anorexia). It is not nausea and vomiting as a side effect of paroxetine administration. Because Johnson does not contemplate or address applicants problem, Johnson can not anticipate or render obvious applicants solution.

Applicants contend that nothing in Johnson renders obvious their invention as currently claimed. Applicants respectfully request that the rejection here be withdrawn.

Applicants therefore submit that all reasons for rejection have been addressed and that the claims, as amended, are allowable. Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned attorney at the number indicated below.

Respectfully submitted,



Wayne J. Dustman  
Attorney for Applicants  
Registration No. 33,870

SMITHKLINE BEECHAM CORPORATION  
Corporate Intellectual Property - UW2220  
P.O. Box 1539  
King of Prussia, PA 19406-0939  
Phone (610) 270-5023  
Facsimile (610) 270-5090

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

Applicants note that all of the previously pending claims have been deleted and replaced by a new claim set. As such, a marked-up version of the claims is not necessary.